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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,361	11/26/2003	Yizhong Gu	PB0105	1196

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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 05/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,361	GU ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 November 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-28,30-32,35-42,45-47,50-52,55 and 57-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *See Continuation Sheet* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims subject to restriction and/or election requirement are 21-28,30-32,35-42,45-47,50-52,55 and 57-61.

DETAILED ACTION

Status of the Application

[1] The Art Unit location of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Art Unit 1656.

[2] Claims 21-28, 30-32, 35-42, 45-47, 50-52, 55, and 57-61 are pending in the application.

[3] Applicant's preliminary amendment to the specification and the claims, filed on 11/26/2003, is acknowledged. The claim listing filed on 11/26/2003 replaces all prior versions and listings of the claims.

[4] In view of numerous applications to which priority is claimed, applicant is requested to indicate which, if any, of the priority applications discloses the elected invention. This will allow the examiner to focus on more substantive issues in the examination of the application.

[5] In the interest of compact prosecution, it is suggested that applicant update the status of application 09/866,108 in the claim to priority in the specification at p. 1. According to USPTO records, the application has issued as US Patent 6,686,188.

Election/Restrictions

[6] Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 21-22, 35, 45, 50, and 57-60, drawn to an isolated polypeptide, a pharmaceutical composition thereof, a diagnostic composition, and a fusion protein, classified in class 435, subclass 196.

II. Claims 23, 36, 46-47, and 51-52, drawn to an isolated antibody, a pharmaceutical composition thereof, and a diagnostic composition, classified in class 530, subclass 387.9.

III. Claim 28, drawn to a transgenic non-human animal or plant modified to contain a nucleic acid, classified in class 800, subclass 13.

IV. Claim 30, drawn to a transgenic non-human animal unable to express the endogenous orthologue of a polypeptide, classified in class 800, subclass 13.

V. Claims 37 and 39, drawn to a purified agonist of a polypeptide and a pharmaceutical composition thereof, classified in class 514, subclass 789.

VI. Claims 38 and 40, drawn to a purified antagonist of a polypeptide and a pharmaceutical composition thereof, classified in class 514, subclass 789.

VII. Claims 24-25, drawn to a method of identifying binding partners for a polypeptide, classified in class 435, subclass 19.

VIII. Claim 26, drawn to a method of modulating the expression of a nucleic acid, classified in class 514, subclass 789.

IX. Claim 27, drawn to a method of modulating an activity of a polypeptide, classified in class 514, subclass 789.

X. Claim 31, drawn to a method of diagnosing a disease caused by mutation in human hGDMLP-1, classified in class 435, subclass 6.

XI. Claim 32, drawn to a method of diagnosing or monitoring a disease caused by altered expression of human hGDMLP-1, classified in class 435, subclass 6.

XII. Claim 41, drawn to a method for treating or preventing a disorder associated with decreased expression or activity of human hGDMLP-1 by administering a pharmaceutical composition comprising a polypeptide, classified in class 514, subclass 2.

XIII. Claim 42, drawn to a method for treating or preventing a disorder associated with increased expression or activity of human hGDMLP-1 by administering a pharmaceutical composition comprising an antibody, classified in class 514, subclass 2.

XIV. Claim 55, drawn to a method for detecting a target nucleic acid in a sample, classified in class 435, subclass 6.

XV. Claim 61, drawn to a method of screening for agents that modulate the expression of hGDMLP-1, classified in class 435, subclass 19.

[7] The inventions are distinct, each from the other because:

[8] The polypeptide of group I and the antibody of group II are patentably distinct for the following reasons: While the inventions of both group I and group II are polypeptides, in this instance the polypeptide of group I is a single chain molecule that functions as an enzyme, whereas the polypeptide of group II encompasses antibodies

including IgG which comprises 2 heavy and light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group I and the antibody of group II are structurally distinct molecules; any relationship between a polypeptide of group I and an antibody of group II is dependent upon the correlation between the scope of the polypeptides that the antibody or binding partner binds and the scope of the antibodies or binding partners that would be generated using the polypeptide. In this case, the polypeptide of group I is a large molecule which contains potentially hundreds of regions to which an antibody or binding partner may bind, whereas the antibody of group II is defined in terms of its binding specificity to a small structure within, *e.g.,* SEQ ID NO:3. Thus the polypeptide of group I would result in the production of antibodies or binding partners outside the scope of group II. Therefore the polypeptide and antibody are patentably distinct. Furthermore, searching the inventions of groups I and II together would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody each require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibody of group II. Furthermore, antibodies which bind to an epitope of a polypeptide of group I may be known even if a polypeptide of group I is novel. Similarly, an amino acid sequence search for fragments of the polypeptide is required to determine the novelty and nonobvious of the antibodies of group II, however such a

search is not required or sufficient to identify all of the polypeptides of group I. In addition, the technical literature search for the polypeptide of group I and the antibody of group II are not coextensive, e.g., antibodies or binding partners may be characterized in the technical literature prior to discovery of or sequence of their binding target.

[9] The polypeptide of group I and transgenic animal or plant of group III are patentably distinct inventions for the following reasons. Polypeptides and transgenic organisms are structurally and functionally distinct entities. The polypeptide of Group I is related to the transgenic organism of group III by virtue of the transgenic organism comprising a nucleic acid encoding the polypeptide of Group I. Any relationship between the encoding nucleic acid of the transgenic organism and the polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. Furthermore, depending on the reading frame, the information provided by the polynucleotide of the transgenic organism of group III can be used to make a materially different polypeptide than that of group I.

Furthermore, searching the inventions of groups I and III together would impose a serious search burden. In the instant case, the search of the polypeptides and the search of the transgenic organism are not coextensive. The inventions of Groups I and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Journal articles disclosing a polypeptide would typically not have disclosed a

transgenic animal modified to comprise a nucleic acid encoding that polypeptide. As such, it would be burdensome to search the inventions of groups I and III together.

[10] The polypeptide of Group I is unrelated to the transgenic organism of Group IV and the methods of Groups VIII, X, and XIII. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the transgenic organism of Group IV does not produce the polypeptide of Group I and the polypeptide of Group I and the transgenic organism of Group IV are structurally and functionally distinct entities. Also, the polypeptide of Group I is neither made nor used by the methods of Groups VIII, X, and XIII.

[11] The polypeptide of Group I and the agonist/antagonist of Groups V and VI are distinct for the following reasons. Any relationship between the polypeptide of Group I and the agonist/antagonist of Groups V and VI is dependent upon the structure of the polypeptide of Group I. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the polypeptide and the agonist/antagonist of Groups V and VI are mutually exclusive, are not obvious variants, and are structurally and functionally distinct entities.

[12] The polypeptide of Group I and the methods of Groups VII, IX, XI, XII, XIV, and XV are related as product and process of use. The inventions can be shown to be

distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group I can be used as an antigen in the production of the antibody of Group II.

[13] The transgenic organism of Group III comprising a polynucleotide encoding SEQ ID NO:3 and the antibody of group II, the agonist of group V, and the antagonist of group VI are patentably distinct for the following reasons. Any relationship between the transgenic organism of Group III and the and the antibody of Group II, the agonist of group V, and the antagonist of group VI is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of encoded polypeptide of SEQ ID NO:3. Binding partners, which encompasses small molecule organic compounds and other polypeptides, are structurally distinct molecules. In the present claims, a polynucleotide encoding SEQ ID NO:3 of the transgenic organism of group III will not encode an antibody of group II and the antibody of group II, the agonist of group V, and the antagonist of group VI cannot be encoded by a polynucleotide encoding SEQ ID NO:3 of the transgenic organism of group III. Therefore the antibody, the agonist, and the antagonist and the transgenic organism are patentably distinct. The antibody, the agonist, and the antagonist and transgenic organism are distinct as shown by their status in the art as shown by their different classifications. Furthermore, searching the inventions of groups II, III, V, and VI together would impose a serious search burden since a search of the polynucleotide

encoding SEQ ID NO:3 of the transgenic organism of group III would not be used to determine the patentability of an antibody of group III, an agonist of group V, and an antagonist of group VI, and vice-versa.

[14] The antibody of Group II, the transgenic organism of Group IV, the agonist of Group V, and the antagonist of Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the antibody of Group II, the transgenic organism of Group IV, the agonist of Group V, and the antagonist of Group VI are not disclosed as capable of use together and the antibody of Group II, the transgenic organism of Group IV, the agonist of Group V, and the antagonist of Group VI are structurally and functionally distinct.

[15] The antibody of Group II is unrelated to the methods of Groups VIII, IX, X, XII, XIV, and XV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the antibody of Group II is neither made nor used by the methods of Groups VIII, IX, X, XII, XIV, and XV.

[16] The antibody of Group II and the methods of Groups VII, XI, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In

the instant case the antibody of Group II can be used as an affinity purification reagent in the purification of the polypeptide of Group I.

[17] Inventions III and IV are related as being transgenic organisms. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the transgenic organisms are mutually exclusive and have a different design as the transgenic organism of Group III comprises a nucleic acid encoding SEQ ID NO:3, while the transgenic organism does not. Further, the transgenic organism of Group III would not render the transgenic organism of Group IV obvious to one of ordinary skill in the art.

[18] The transgenic organisms of Groups III-IV and the methods of Groups VII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the transgenic organisms of Groups III-IV are neither made nor used by the methods of Groups VII-XV.

[19] The agonist of Group V and the antagonist of Group VI are unrelated to the methods of Groups VIII and X-XIV. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the agonist of

Group V and the antagonist of Group VI are neither made nor used by the methods of Groups VIII and X-XIV.

[20] The agonist of Group V and the antagonist of Group VI and the methods of Groups VII, IX, and XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the agonist of Group V and the antagonist of Group VI can each be used as an affinity purification reagent in the purification of the polypeptide of Group I.

[21] The methods of Groups VII-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, and they have different designs, modes of operation, and effects. (MPEP § 802.01and § 806.06). In the instant case, the methods of Groups VII-XV comprise different method steps, utilize different products, and yield different results.

[22] MPEP § 803 sets forth two criteria for a proper restriction between patentably distinct inventions: (A) The inventions must be independent or distinct as claimed and (B) There must be a serious burden on the examiner. As shown above, each of the inventions of Groups I-XV are independent or distinct, thus satisfying the first criterion for a proper restriction. MPEP § 803 additionally states that a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search.

Each of the inventions requires a separate patent and non-patent literature and sequence search and thus, co-examination of the inventions of Groups I-XV would be a serious burden on the examiner.

[23] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[24] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Rejoinder

[25] The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Mon to Fri, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656